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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,447	06/09/2000	Barry M. Forman	17302(HL)	1446

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Allergan Inc
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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/590,447	FORMAN ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/19/2004, 3/22/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 31-40* is/are pending in the application.

4a) Of the above claim(s) *37* is/are withdrawn from consideration.

5)☒ Claim(s) *31-36 and 38-40* is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed March 19, 2004 and March 22, 2004 have been entered.

Claims 1-13 and 31-40 are pending. Claim 37 is withdrawn as it is directed to a non-elected invention.

Allowable Subject Matter

Claims 31-36 and 38-40 are allowed over the cited prior art. The cited prior art does not teach or fairly suggest the herein claimed method of treating hypercholesterolemic mammal by employing the compounds of formula (3).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dyslipidemia, hypercholesterolemia, or hypocholesterolemia, does not reasonably provide enablement for othe FXR-mediated pathological conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the instant specification fails to provide information that would allow the skilled artisan to practice the instant

invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

The claims are very broad. They encompass any disorders, clinical or sub-clinical, detectable or non-detectable, pathological conditions that are mediated by FXR. Applicant fails to set forth the criteria that define "FXR mediated pathological conditions". The instant specification gives no guidance or information as to what would be considered FXR- mediated pathological conditions other than dyslipidemia, hyper- or hypocholesterolemia. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these conditions without undue experimentation. In the instant case, only a limited number of "FXR mediated pathological conditions" examples are set forth, thereby failing to provide sufficient working examples. It is noted that

these examples are neither exhaustive, nor define the common symptoms that is being treated. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "FXR mediated pathological condition(s)", necessitating an exhaustive search for the pathological conditions suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Response to arguments

Applicant's arguments filed March 19, 2004 averring the applicant clearly disclosing how to make and use a method of treatment of an FXR-mediated pathological condition have been considered, but are not found persuasive. Examiner notes that applicant does not even define what conditions would be considered as FXR-mediated pathological conditions other than dyslipidemia, hypercholesterolemia, and hypocholesterolemia. In other word, the conditions recited in the claims herein encompass conditions that are not even envisioned by the applicant. The scope of the claims is very broad to the extent that one of skilled in the art would not have known what conditions as treatable by the herein claimed compounds without performing undue experimentation.

Applicant's arguments filed March 19, 2004 averring applicant seeking claim protection, which is commensurate in scope with the enablement provided, have been considered, but are not found persuasive. As discussed above, the scope of the instant

claims is very broad to the extent that encompasses conditions that are not even envisioned by the applicant. The recitation is merely functional. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Applicant's arguments filed March 19, 2004 averring Examiner's failure to provide reasons why the instant disclosure does not enable one skilled in the art to practice the method on further embodiments have been considered, but are not found persuasive. Examiner noted that it is not even know what the so-called "further embodiments" can be. The problem of the claims is that the skilled artisans do not even know what those conditions are. Without such information, it is not possible to tell whether the herein claimed compounds will be able to treat that particular condition(s) or not. Examiner is not required to prove that the herein claimed compounds do not work on certain FXR-mediated conditions. Rather, the test of enablement is whether one reasonably skilled in the art make or use the invention in the full scope of the claim from the disclosure in the patent combined with information known in the art without undue experimentation. In the instant case, the skilled artisan would not have known whether the compounds will work on particular disease simply because it is not known what conditions or disorders would have been considered as FXR-mediated pathological conditions, other than dyslipidemia, hypercholesterolemia, and hypocholesterolemia.

Applicant's arguments filed March 19, 2004 averring the phrase "FXR-mediated pathological conditions" as most precise and accurate term used by Applicant have been considered, but are not found persuasive. As discussed above, the scope of the claims is not clear as to the conditions encompassed by the claims or treatable by the hererin claimed compounds.

Applicant's arguments filed March 19, 2004 averring Applicant not being required to disclose every FXR-mediated pathological condition in the instant specification have

been considered, but are not found persuasive. It is generally true that the applicant not necessarily disclose every conditions treated in the claims; however, if the biological and physiological functions of the particular receptor is not fully known, then claiming the method of modulating such receptor and hopefully to achieve some therapeutic effect for certain conditions associated by the same receptor and yet without knowing what the conditions are would be considered an invitation to experimentation. Therefore, the claims are still properly rejected under 35 USC 112, first paragraph.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent examiner
Art Unit 1617